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7 SPECIAL MASTER

8  
9 UNITED STATES DISTRICT COURT  
10 NORTHERN DISTRICT OF CALIFORNIA

11 RENEE CONTRATTO, on behalf of  
12 herself and the general public,

13 Plaintiff(s),

14 vs.

15 ETHICON, INC. et al., (dba  
16 GYNECARE WORLDWIDE), a  
17 New Jersey Corporation; JOHNSON  
18 & JOHNSON, a New Jersey  
19 Corporation; LIFECOREE  
BIOMEDICAL, INC., a Florida  
Corporation; and DOES 1-25,

20 Defendant(s).

21 CASE #: C03-3804 MJJ (BZ)  
JAMS Ref#: 1100043994

22  
23 SPECIAL MASTER'S ORDER NO.  
24 5: LIFECOREE'S MOTION TO  
25 MAINTAIN CONFIDENTIALITY  
OF DOCUMENTS AND  
DEPOSITION TESTIMONY (Hrg.  
8/24/05)

26 On August 24, 2005, Lifecore's motion to maintain the confidentiality of documents  
27 produced and deposition testimony in this case was heard by Special Master Martin Quinn.  
Counsel for all parties were present in person or by telephone. Having considered all the  
argument submitted by the parties and reviewed all the documents in question, the Special  
Master orders as follows.

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1                   I.        Relevant Facts

2                   On February 9, 2004, Judge Jenkins signed a stipulated protective order that allowed  
 3 defendants to designate documents as confidential. Defendants Lifecore and Ethicon designated  
 4 virtually all the documents they produced ("all but a few hundred out of three to four hundred  
 5 thousand documents," according to Judge Zimmerman's 2/7/05 Order). Plaintiff duly objected,  
 6 and Lifecore and Ethicon moved for an order to uphold the confidential designation of 13  
 7 disputed documents. In an Order Denying Defendants' Motion to Uphold Confidential  
 8 Designation of Documents, dated 2/7/05, Judge Zimmerman found that none of the 13  
 9 documents was entitled to confidentiality protection under FRCP 26(c) either as a "trade secret"  
 10 or as "confidential research, development, or commercial information." Judge Zimmerman  
 11 based his Order on both (1) the absence of any detailed evidence to show that the information  
 12 was truly secret and that its disclosure would harm Lifecore, and (2) his own inspection of the  
 13 documents.  
 14

15                   In light of the 2/7/05 Order, the parties have tried to reach agreement on which of the  
 16 remaining documents should remain confidential. While they have been partially successful,  
 17 disputes still remain. By this motion, Lifecore once again asks the court to endorse its  
 18 confidentiality designations of about 25 documents and five groups of deposition testimony.  
 19 Plaintiff argues that, apart from limited redactions of portions of some of the documents that  
 20 contain numeric details of manufacturing formulas, none of the documents or testimony is  
 21 entitled to be designated confidential.

22                   II.        Analysis23                   A.        General Principles

24                   The Special Master approaches the present motion guided by the analysis and  
 25 conclusions of Judge Zimmerman's 2/7/05 Order that found that very similar documents were  
 26 not confidential. However, the Special Master is also mindful that Lifecore has submitted very  
 27 significantly more detailed evidence in support of confidentiality than was before Judge  
 28 Zimmerman. Therefore, while adhering to the legal principles in the 2/7/05 Order, the Special

1 Master has reviewed carefully and relied upon the declaration of James Hall, Lifecore's Director  
2 of Manufacturing and Operations since 2001, and the evidence attached to the two declarations  
3 of Thomas Watson, one of Lifecore's counsel.

4 All but a few of the documents and testimony relate to two periods of research and  
5 investigation of "globules", or "particulates," that seemed to form in Intergel during the  
6 manufacturing process. Plaintiff alleges that her injuries were caused by Intergel "contaminated  
7 with small particulates of ferric or iron hydroxide." [Watson decl., Exh. F] The first period of  
8 investigation was in 1996-1998 when the product was being readied for market; the second was  
9 in 2003 after Intergel had been removed from the market.  
10

11 An important consideration in evaluating this motion is that Judge Zimmerman found that  
12 a 6/19/03 Lifecore memo about the second globule investigation [Talley decl., Exh. 3] was not  
13 confidential. His 2/7/05 Order states, at p. 11, that the document does "not appear to contain  
14 secret information, nor does it appear that the public disclosure of the documents would harm  
15 defendants. . . I have determined that the document only generally summarizes past research  
16 performed on the product and does not reveal proprietary formulas for the product or contain  
17 confidential research procedures." The 6/19/03 memo summarizes in considerable detail  
18 Lifecore's preliminary findings and conclusions, the test procedures employed, and the  
19 corrective actions Lifecore was contemplating. Given that this document is already public, it  
20 makes little sense to keep documents confidential that contain less specific information about the  
21 globule investigation.

22 Notwithstanding defendants' arguments, the Special Master concludes that the mere  
23 existence and the general parameters of these two investigations are not entitled to  
24 confidentiality under Rule 26 (c). The fact that a pharmaceutical company is investigating the  
25 efficacy of its product, at least under these circumstances, is neither a trade secret nor  
26 confidential commercial information. Nor is non-specific information about the scope or  
27 conclusions of such investigations entitled to confidentiality. On the contrary, Lifecore is  
28 entitled to protect specific information about those investigations that would give a competitor a

1 road map of how to avoid similar manufacturing problems, or would reveal unique, non-obvious  
 2 features of Intergel's makeup or the process for manufacturing it. News media recently reported  
 3 that known problems with a heart defibrillator, that caused short circuits and apparently one  
 4 death, were not made public because of confidentiality concerns. This incident illustrates the  
 5 public interest in prompt disclosure when manufacturers investigate problems with their medical  
 6 devices – in the absence of clear danger of competitive harm.  
 7

8       B.     The Disputed Documents

9       With reference to the tabbed Exhibits to the Hall declaration supplied by counsel for  
 10 Lifecore, the Special Master finds that the designated portions of the following documents, and  
 11 related deposition testimony, may not properly be designated as Confidential: Tabs A, B, C, D,  
 12 E, G, H, I, K, N, O, P, S, T, U, W and Y. All these documents contain only very general  
 13 descriptions of investigations, research or processes. Many of them are close to 10 years old.  
 14 Much of the material is obvious (e.g., that Lifecore would consider animal testing). Some of  
 15 them are so similar to the 6/19/03 memorandum that Judge Zimmerman ordered disclosed that  
 16 there is no further basis to keep these documents confidential.

17       The Special Master finds that all or part of the designated portions of the following  
 18 documents may properly be designated as Confidential: Tabs F, J, L, M, Q, R and X.  
 19 Deposition testimony related directly to the confidential portions of these documents may also be  
 20 designated as Confidential.

21       Tab F: 8/18/03 Investigation Summary. The Root Cause Analysis (60868-60871) and  
 22 the Historical Data and Attachments (60873-60887) may be designated Confidential because  
 23 they contain specific information about product makeup, manufacturing processes and research  
 24 procedures. The remainder of the designated portion may not be designated Confidential.

25       Tab J: Portion of PMA re Stability Studies, 11/24/98. The entire designated portion may  
 26 be designated Confidential. It contains specific information about storage procedures and  
 27 specifications for the product that could be of competitive value if disclosed. There is no  
 28 compelling public interest in disclosure.

1 Tab L: PMA Amendment, 9/99. Pages 7148, 7162 and 7163 may be designated  
2 Confidential since they contain specific information about product specifications and test  
3 procedures. The rest of the designated portion must be disclosed.

4 Tab M: Stability Study, 2/8/00. The entire designated portion may be designated  
5 Confidential because it contains details of protocols and research results concerning the stability  
6 of the product. There is no compelling public interest in disclosure.

7 Tab Q: Emails and related documents re Intergel globule investigation. The 3/4/03 email  
8 (01372) may not be designated Confidential. The remaining designated portions of the  
9 documents may be designated Confidential, since they discuss specific procedures and results of  
10 the investigation at a level of detail that could be of competitive value if disclosed.

12 Tab R: 3/26/03 Background Investigation and Quality Audit, and 8/12/03 memo re  
13 investigation re globules. Pages BAC 013746 (the first page of the document), and the 8/12/03  
14 memo (BAC 005547) may not be designated Confidential. The remaining designated portions of  
15 the document may be designated confidential since they discuss procedures and results of the  
16 quality audit at a level of detail that could be of competitive value if disclosed.

17 Tab X: Vital Pharma Quality Control Procedure, 1/4/03. The entire designated portion  
18 of the document may be designated Confidential, since it contains specific manufacturing  
19 procedures that could be of comparative value if disclosed. There is no compelling public  
20 interest in disclosure.

21 C. The Disputed Deposition Testimony Not Related to a Document

22 The designated portions of the testimony of Douglas Johns, and of pages 22-37 of the  
23 testimony of Jackie Kieser, may be designated Confidential. The remainder of the Kieser  
24 deposition, and the entirety of the Bracke, diZerega and Keyport depositions may not be  
25 designated Confidential.

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### III. Order

Accordingly, good cause appearing, it is ORDERED that defendants' motion is GRANTED IN PART:

1. Defendants may designate as Confidential the portions of the documents and deposition testimony identified above. All remaining portions of the disputed documents at issue on this motion shall not be subject to confidentiality under the protective order entered in this case.

2. The JAMS charges for the Special Master to hear this motion shall be paid 50% by Lifecore and 50% by plaintiff.

Dated: September 13, 2005

Martin Quinn, Special Master